IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC., Plaintiffs, v. CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH, Defendants.	Redacted: Public Version C.A. No. 18-095-GMS [redacted]

DECLARATION OF KEVIN J. DEJONG IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR STAY

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Dated: April 16, 2018

I, Kevin J. DeJong, declare as follows:

1. I am an associate in the law firm of Goodwin Procter LLP, counsel for Defendants Celltrion Inc., Celltrion Healthcare Co. Ltd., Teva Pharmaceuticals USA Inc., and Teva Pharmaceuticals International GmbH. I submit this declaration in support of Defendants' Motion to Dismiss or Stay. I have personal knowledge of the facts set forth below, and if called as a witness, could and would competently testify thereto.

2. Attached hereto as exhibit A is a true and correct copy of the First Amended Complaint filed by Defendants under seal in the Northern District of California, Case No. 3:18-cv-274, on February 8, 2018.

I declare under penalty of perjury that the foregoing is true and correct. Executed on April 16, 2018.

/s/ Kevin J. DeJong
Kevin J. DeJong

CERTIFICATE OF SERVICE

I, Nathan R. Hoeschen, hereby certify that on April 16, 2018, this document was served on the persons listed below in the manner indicated:

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REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS INTERNATIONAL GMGH, and TEVA PHARMACEUTICALS USA, INC.

Plaintiffs,

v.

GENENTECH, INC., HOFFMANN LA-ROCHE INC. and CITY OF HOPE,

Defendants.

Case No. 3:18-cv-274-WHO

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT NON-INFRINGEMENT, INVALIDITY, AND/OR UNENFORCEABILITY

Plaintiffs Celltrion, Inc. ("Celltrion Inc."), Celltrion Healthcare, Co. Ltd. ("Celltrion Healthcare") (collectively "Celltrion"), Teva Pharmaceuticals International GmbH ("TPIG"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively "Teva") (collectively with Celltrion, Celltrion Healthcare, and TPIG, "Plaintiffs") bring this action for declaratory judgment of patent non-infringement, invalidity and unenforceability against Defendants Genentech, Inc. ("Genentech"), Hoffmann-La Roche Inc. ("Roche") and City of Hope. This is a case to protect Celltrion and Teva's efforts to bring more affordable drugs to market. Celltrion and Teva have developed technology to manufacture antibodies known to be effective in treating several types of cancer and other serious diseases, and have sought FDA approval to market a product containing these antibodies. Genentech has claimed that forty patents will be infringed by Celltrion and Teva. Rather than focusing their assertion, Defendants have rested on a complex series of patents from two dozen patent families. As Celltrion has already demonstrated to Genentech, these allegations are wrong and the panoply of vague allegations are simply intended to interfere with Celltrion and Teva's entry into the market. This case seeks to clear the underbrush of Defendants' allegations to ensure that Celltrion and Teva's biosimilar product can help millions of people facing life-threatening diseases today.

NATURE OF THE CASE

1. This is an action for declaratory judgment of non-infringement, invalidity, and unenforceability relating to the following patents:

(i) U.S. Patent No. 6,331,415 ("the '415 patent");

(ii) U.S. Patent No. 6,339,142 ("the '142 patent");

(iii) U.S. Patent No. 6,407,213 ("the '213 patent");

(iv) U.S. Patent No. 6,417,335 ("the '335 patent");

(v) U.S. Patent No. 6,489,447 ("the '447 patent");

(vi) U.S. Patent No. 6,586,206 ("the '206 patent");

(vii) U.S. Patent No. 6,610,516 ("the '516 patent");

(viii) U.S. Patent No. 6,620,918 ("the '918 patent");

(ix) U.S. Patent No. 6,627,196 ("the '196 patent");

(x) U.S. Patent No. 6,716,602 ("the '602 patent");

(xi) U.S. Patent No. 7,371,379 ("the '379 patent");

(xii) U.S. Patent No. 7,390,660 ("the '660 patent");

(xiii) U.S. Patent No. 7,449,184 ("the '184 patent");

(xiv) U.S. Patent No. 7,485,704 ("the '704 patent");

(xv) U.S. Patent No. 7,501,122 ("the '122 patent");

(xvi) U.S. Patent No. 7,807,799 ("the '799 patent");

(xvii) U.S. Patent No. 7,846,441 ("the '441 patent");

(xviii) U.S. Patent No. 7,892,549 ("the '549 patent");

(xix) U.S. Patent No. 7,923,221 ("the '221 patent");

(xx) U.S. Patent No. 7,993,834 ("the '834 patent");

(xxi) U.S. Patent No. 8,076,066 ("the '066 patent");

(xxii) U.S. Patent No. 8,357,301 ("the '301 patent");

(xxiii) U.S. Patent No. 8,425,908 ("the '908 patent");

(xxiv) U.S. Patent No. 8,440,402 ("the '402 patent");

(xxv) U.S. Patent No. 8,460,895 ("the '895 patent");

(xxvi) U.S. Patent No. 8,512,983 ("the '983 patent");

(xxvii) U.S. Patent No. 8,574,869 ("the '869 patent");

(xxviii) U.S. Patent No. 8,633,302 ("the '302 patent");

(xxix) U.S. Patent No. 8,691,232 ("the '232 patent");

(xxx) U.S. Patent No. 8,771,988 ("the '988 patent");

(xxxi) U.S. Patent No. 8,822,655 ("the '655 patent");

(xxxii) U.S. Patent No. 9,047,438 ("the '438 patent");

(xxxiii) U.S. Patent No. 9,080,183 ("the '183 patent");

(xxxiv) U.S. Patent No. 9,249,218 ("the '218 patent");

(xxxv) U.S. Patent No. 9,428,548 ("the '548 patent");

(xxxvi) U.S. Patent No. 9,428,766 ("the '766 patent");

(xxxvii) U.S. Patent No. 9,487,809 ("the '809 patent"); and

(xxxviii) U.S. Patent No. 9,714,293 ("the '293 patent") (collectively, "the patents-in-suit").

2. According to Genentech, the patents-in-suit relate to an antibody product called trastuzumab, which Genentech markets under the brand name Herceptin®. Herceptin® is approved by the FDA for the treatment of HER2 overexpressing breast cancer, and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

3. On information and belief, Roche is an owner of certain patents-in-suit, and has provided Genentech with the rights to enforce certain of the patents-in-suit.

4. On information and belief, each patent-in-suit is owned by at least one of Genentech, Roche, or City of Hope.

5. A substantial controversy exists between Plaintiffs, on the one hand, and Genentech, Roche, and City of Hope, on the other hand, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Celltrion Healthcare, Celltrion Inc., and TPIG entered into a business collaboration agreement to commercialize CT-P6, a biosimilar to Herzuma®. Celltrion Inc. submitted an Abbreviated Biologics License Application ("aBLA") to the FDA under 42 U.S.C. § 262(k) of the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") for licensure of a trastuzumab biological product (hereinafter, "biosimilar product," "CT-P6," or "Herzuma®") that is highly similar to Herceptin®. Teva USA will sell and distribute the CT-P6 product in the United States. The FDA accepted Celltrion Inc.'s biosimilar application on July 28, 2017. Celltrion Inc. provided Genentech with a copy of its aBLA and other detailed information regarding the manufacturing processes used to make Herzuma® and, in response, Genentech identified the patents which Genentech alleges could reasonably be asserted against Plaintiffs if they were to manufacture, use, offer for sale, or sell in the United States, or import into the United States, the biosimilar product. Celltrion Inc. then provided Genentech with a detailed statement regarding the invalidity, unenforceability, and/or non-infringement of the patents that Genentech identified, along with

citations to the aBLA and other manufacturing information that Celltrion produced to Genentech. In response, Genentech provided Plaintiffs with a statement purporting to contain the factual and legal basis of Genentech's opinion that some of the patents-in-suit would be infringed by the commercial marketing of the biosimilar product.

6. Pursuant to 42 U.S.C. § 262(*l*)(8)(A) [redacted], Celltrion Inc. provided Genentech with notice that the first commercial marketing of Herzuma® will commence no earlier than 180 days from the date of the notice.

PARTIES

7. Celltrion Inc. is a corporation organized and existing under the laws of the Republic of Korea, with a place of business at 23, Academy-ro, 51beon-gil, Yeonsu-gu, Incheon, Korea.

8. Celltrion Healthcare, Co. Ltd. is a corporation organized under the laws of the Republic of Korea, having its place of business at 23, Academy-ro 51, Yeonsu-gu, Incheon, 406-840, Korea.

9. Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a place of business at 1090 Horsham Road, North Wales, PA 19454-1090.

10. TPIG is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and a place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

11. On information and belief, Defendant Genentech, Inc. is a corporation with its principal place of business in this District at 1 DNA Way, South San Francisco, CA 94080.

12. On information and belief, Defendant City of Hope is a not-for-profit organization organized and existing under the laws of California, having its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

13. On information and belief, Defendant Hoffmann La-Roche Inc. is a company organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

JURISDICTION AND VENUE

14. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

15. Celltrion Inc. provided to Genentech the aBLA required under 42 U.S.C. § 262(*l*)(2)(A), and also provided additional manufacturing information to Genentech. In response, Genentech identified the patents-in-suit pursuant to 42 U.S.C. § 262(*l*)(3)(A), which Genentech alleges could reasonably be asserted against Plaintiffs if they were to manufacture, use, offer for sale, or sell in the United States, or import into the United States, the biosimilar product. Celltrion Inc. provided Genentech with a detailed statement why Plaintiffs will not infringe any of the patents-in-suit. Genentech then provided Plaintiffs with a statement purporting to contain the factual and legal basis of Genentech's opinion that some of the patents-in-suit would be infringed by the commercial marketing of Celltrion's biosimilar product.

16. On [redacted], Celltrion provided notice of commercial marketing to Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A).

17. The Court has personal jurisdiction over Genentech because Genentech has its headquarters and principal place of business in the State of California, in this District. On information and belief, Genentech's South San Francisco campus is its headquarters for its pharmaceutical operations in the United States. Genentech also maintains multiple other facilities in California, including a biotech manufacturing and clinical operations complex in Oceanside, California, and a biotechnology manufacturing plant in Vacaville, California.

18. Upon information and belief, Genentech markets, distributes and sells pharmaceutical products, including Herceptin®, in California, including in this District. Genentech's continuous and systematic corporate operations within California are so substantial and of such a nature to justify suit against it on causes of action arising from dealings entirely distinct from those activities.

19. The Court also has personal jurisdiction over Genentech because, among other reasons, Genentech's activities in California gave rise to this action. For example, Genentech, which is located in this District, directed its counsel to send Plaintiffs' counsel (i) correspondence related to the BPCIA exchanges described above, (ii) a list of patents that it purports could reasonably be asserted against Plaintiffs, and (iii) a statement that purports to describe, among other things, the factual and legal basis of Genentech's opinion that patents that it owns, or for which it is an exclusive licensee, will be infringed by the commercial marketing of the biosimilar product, all within this District and the State of California.

20. The Court has personal jurisdiction over City of Hope because, among other reasons, upon information and belief, it is organized under the laws of the State of California and has its principal place of business in California. Upon information and belief, City of Hope is the co-owner of one or more patents-in-suit. City of Hope also maintains a place of business for fundraising and development in this District at 55 Hawthorne Street, Ste. 450, San Francisco, California 94105.

21. This Court also has personal jurisdiction over City of Hope because City of Hope has purposefully directed various activities at this District which gave rise to this action. For example, on information and belief, City of Hope collaborated with San-Francisco-based Genentech to research and/or develop the subject matter of certain patents-in-suit and/or entered into contractual agreements with San-Francisco-based Genentech regarding certain patents-in-suit. In addition, on information and belief, City of Hope has knowingly consented to and/or collaborated with San-Francisco-based Genentech's enforcement actions regarding one or more of the patents-in-suit.

22. The Court has personal jurisdiction over Roche because, upon information and belief, Roche researches, manufactures, and markets branded drug products, and continuously and systematically conducts business throughout the United States, including in California. Roche is licensed to do business in the State of California. Roche's headquarters for commercial operations are in this District at 1 DNA Way, South San Francisco, CA 94080. Roche's continuous and

systematic corporate operations within California are so substantial and of such a nature to justify suit against it on causes of action arising from dealings entirely distinct from those activities.

23. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because, among other reasons, Genentech, City of Hope, and Roche all reside and are subject to personal jursidiction in this District for purposes of this action as set forth above. In addition, venue is proper in this district because a substantial part of the events that gave rise to this action occurred in this District. For example, on information and belief, one or more of Genentech, City of Hope, and Roche collaborated in this District regarding research and/or development of the subject matter of certain patents-in-suit and/or entered into contractual agreements with San Francisco-based Genentech regarding certain patents-in-suit. In addition, on information and belief, one or more of City of Hope and Roche have knowingly consented to and/or collaborated with San-Francisco-based Genentech's enforcement actions regarding one or more of the patents-in-suit. Moreover, Genentech, which is located in this District, has directed certain activities at Plaintiffs' counsel relating to the enforcement of the patents-in-suit, including the transmission of (i) correspondence related to the BPCIA exchanges described above, (ii) a list identifying the patents-in-suit among those patents that Genentech believes could reasonably be asserted against Plaintiffs following the submission of their subsection (k) application, and (iii) a statement that purports to describe Genentech's opinions regarding the infringement, validity, and enforceability of the patents-in-suit. Furthermore, Genentech and City of Hope have litigated in this District at least 11 separate actions relating to one or more of the patents-in-suit, including those having civil action numbers 5-15-cv-01238; 3-13-cv-02045; 4-13-cv-00919; 4-11-cv-02410; 3-11-cv-01925; 5-10-cv-04255; 5-10-cv-02037; 3-10-cv-00675; 3-09-cv-04919; 5-08-cv-05590; 3-08-cv-04909; 4-04-cv-05429; 3-04-cv-01910; 3-03-cv-01603; 3-01-cv-03560; 5-01-cv-20434; 3-98-cv-03926.

FACTUAL BACKGROUND

24. Celltrion was founded in 2002 with the mission of developing and supplying medicines at an affordable cost to patients suffering from life-threatening and debilitating diseases. Such patients previously had limited access to advanced therapeutics such as biologic drugs due to

their high cost and relative shortage of availability. Celltrion develops, manufactures, and distributes biosimilars and novel biologics to introduce competition in the pharmaceutical market for antibody biologics, to offer alternative solutions for previously limited, high-cost therapies. Because of their complexity, biologic drugs require substantially more effort, monetary resources and technical expertise to develop than traditional drugs that are synthesized chemically.

25. Over the last 15 years, Celltrion has made significant investments in human resources, facilities, and technology to become a global leader in biologics. Celltrion spear-headed global efforts to produce a biosimilar version of monoclonal antibody biologics, and received marketing approval for the world's first biosimilar monoclonal antibody in 2012. In 2014, Celltrion achieved another global first, and obtained approval for a biosimilar oncology monoclonal antibody. Celltrion has since introduced other biosimilars for the treatment of various types of cancer and autoimmune diseases in Europe, Korea, and Canada. Since its founding, Celltrion has devoted itself to improving patient access to advanced and novel therapeutics for the treatment of life-altering and life-threatening diseases. Celltrion has invested in major cell lines and core technologies to develop biosimilars and novel drugs and vaccines.

26. Celltrion has devoted significant time, effort, and substantial monetary resources to the development of Herzuma®. With its deep experience in biologics development and manufacturing, Celltrion designed the manufacturing process and process controls that have been and will be used to make Herzuma®, including, among other things, developing the cell culture, harvest, and numerous purification steps to manufacture and purify the Herzuma® antibody. Celltrion also conducted numerous clinical studies in which it successfully tested Herzuma® in humans. In the end, Celltrion generated comprehensive analytical, pharmacokinetic, pharmacodynamics, and clinical data that was submitted to the FDA as part of the FDA-approval process.

27. In 2016, Celltrion, Inc., Celltrion Healthcare, and TPIG entered into an exclusive partnership to commercialize Herzuma® in the United States. Teva USA will market Herzuma® in the United States. Teva is a leading global pharmaceutical company that delivers high-quality,

patient-centric healthcare solutions used by millions of patients every day. Teva has a portfolio of more than 1,800 molecules and has a world-leading position in innovative treatments. Teva is also a leader in biologic and biosimilar development.

Congress Enacts Legislation Creating a Regulatory Pathway for Biosimilar Biological Products

28. With the passage of the BPCIA, Congress created a new pathway for FDA review and approval of "biosimilar" biological products, as well as new mechanisms to resolve patent disputes that may arise with respect to such products.

29. "The BPCIA governs a type of drug called a biosimilar, which is a biologic product that is highly similar to a biologic product that has already been approved by the Food and Drug Administration (FDA)." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

30. The BPCIA sets forth an abbreviated pathway for FDA approval of biosimilars. 42 U.S.C. § 262(k). To obtain approval through the BPCIA's abbreviated process, an applicant must show that its biosimilar product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two products in terms of "safety, purity, and potency." 42 U.S.C. § 262(k)(2). Under the BPCIA, an applicant may not submit an application until 4 years after the reference product is first licensed, and the FDA may not license a biosimilar until 12 years after the reference product is first licensed. 42 U.S.C. § 262(k)(7).

31. The reference product sponsor (also known as an "RPS") may have patents relating to the biological product, as well as therapeutic uses for and/or processes used to manufacture the biological product, that it believes may be relevant to the biosimilar product. In recognition that there may be patent disputes between the RPS and the biosimilar applicant, "[t]he BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent] infringement." *Sandoz*, 137 S. Ct. at 1671 (citing 42 U.S.C. § 262(*l*)).

32. The BPCIA describes a process whereby the RPS and the biosimilar applicant may exchange information in advance of an action for patent infringement. *First*, the process begins when the applicant provides "a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to

manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). In addition, the applicant "may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." 42 U.S.C. § 262(*l*)(2)(B). *Second*, the BPCIA states that the RPS shall provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor . . . if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A). *Third*, the BPCIA requires the applicant who chooses to exchange information in advance of an action for patent infringement to provide a "detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(B)(ii)(I). Alternatively, the applicant can provide "a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires." 42 U.S.C. § 262(*l*)(3)(B)(ii)(II). *Last*, the BPCIA states that the RPS "shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I)." 42 U.S.C. § 262(*l*)(3)(C).

33. Following the information exchange, the BPCIA requires the RPS and the applicant to engage in "good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6) [of the statute]." 42 U.S.C. § 262(*l*)(4). If the subsection (k) applicant and RPS disagree over which patents should be litigated, the statute

provides for a mechanism of further exchanges to determine which patent(s) will be the subject of a paragraph (6) patent litigation. 42 U.S.C. § 262(*l*)(4)(B)-(5). While the procedure and timing depend on whether the RPS and the applicant can reach agreement, the process may result in a statutorily defined action for patent infringement. 42 U.S.C. § 262(*l*)(6).

34. Paragraph (*l*)(8) of the BPCIA states that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Once the applicant's notice of commercial marketing is received by the RPS, any limitation under the BPCIA on bringing an action under section 2201 of title 28 for a declaration of rights concerning patent infringement, validity and/or enforceability is lifted. 42 U.S.C. § 262(*l*)(9). "If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the [RPS] nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B)." 42 U.S.C. § 262(l)(9)(A).

35. Any manufacture and use of CT-P6 by any of the Plaintiffs prior to commercial marketing was and is solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

The Parties' Exchanges Following the Filing of Celltrion's Subsection (k) Application for Approval of The Biosimilar Product

36. According to the FDA's "Purple Book," Genentech's Herceptin® was first approved on September 25, 1998.

37. On May 30, 2017, Celltrion submitted its Biologics License Application ("BLA") for Herzuma® pursuant to 42 U.S.C. § 262(k). Celltrion Inc.'s aBLA was filed after the expiration of the 4- year and 12-year statutory periods provided by 42 U.S.C. § 262(k)(7). Celltrion received notification from the FDA that its aBLA had been accepted for review on July 28, 2017.

38. On August 1, 2017, prior to the deadline under 42 U.S.C. § 262(*l*)(2)(A) for Celltrion to produce its aBLA, Genentech wrote a letter to Celltrion requesting that Celltrion produce vaguely defined categories of information relating to the processes used in the production of Herzuma® "irrespective of whether it is contained in the aBLA," but did not list any patents to which the information sought might be relevant.

39. On August 11, 2017, Celltrion, Inc. timely sent to Genentech its disclosure pursuant to 42 U.S.C. § 262(*l*)(2)(A), including the aBLA for Herzuma® and other detailed information regarding the manufacturing processes used to make Herzuma®. Specifically, Celltrion, Inc. produced its aBLA, and upstream and downstream manufacturing reports describing in detail the manufacturing process for Herzuma®. Celltrion Inc.'s production of more than 280,000 pages of technical details and batch records described, among other things, (i) the source, history, and generation of the cell substrate, (ii) the cell culture and harvest process, (iii) each and every purification process step, and (iv) raw materials used during the manufacture of Herzuma®.

40. Celltrion Inc.'s production contained sufficiently detailed information regarding its biosimilar product and manufacturing processes, which complied with the production requirements in 42 U.S.C. § 262(*l*)(2)(A)-(B) and enabled Genentech to undertake its obligations under 42 U.S.C. § 262(*l*)(3)(A).

41. On October 10, 2017, Genentech provided Celltrion, Inc. with its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) ("the (3)(A) list") that Genentech "believe[d] could reasonably be asserted against Celltrion's proposed CT-P6 product based upon a review of the product's aBLA filing." Genentech's (3)(A) list included a total of 40 patents, including all of the patents-in-suit. 42 U.S.C. § 262(*l*)(3)(A) requires an RPS to identify the patents for which the RPS "believes a claim of patent infringement could reasonably be asserted by [the RPS] or by a patent owner that has granted an exclusive license to [the RPS] with respect to [the reference product]." 42 U.S.C. § 262(*l*)(3)(A). Therefore, by identifying a patent on its (3)(A) list, Genentech has represented that Genentech has the right to assert the patent as the patent owner, or exclusive licensee.

42. On November 7, 2017, Celltrion, Inc. timely responded to Genentech's (3)(A) list by providing Genentech with a statement pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(II), and further providing Genentech, pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(I), with a 533-page detailed statement that describes on a claim-by-claim basis the factual and legal bases for Celltrion Inc.'s opinion that patents included on Genentech's (3)(A) list are not infringed and/or are invalid or unenforceable (Celltrion's "(3)(B) statement"). Celltrion, Inc. annotated its non-infringement contentions with detailed citations to its aBLA and the other documents that Celltrion had produced to Genentech.

43. Despite being under no obligation to do so, throughout the summer and fall of 2017, Celltrion, Inc. worked diligently to obtain, and did obtain, the right to disclose to Genentech the documents of [redacted] to Genentech that were potentially relevant to the CT-P6 manufacturing process. Celltrion, Inc. produced these documents, along with recent FDA correspondence related to Celltrion Inc.'s aBLA, with Celltrion Inc.'s (3)(B) statement. Celltrion Inc.'s extraordinary efforts alleviated the need for Genentech to seek third party discovery to obtain these documents.

44. Thus, Celltrion Inc.'s (3)(B) statement identifying the bases for Celltrion Inc.'s non-infringement of Genentech's (3)(A) patents cited extensively to documents that Celltrion Inc. had produced to Genentech. Therefore, contrary to any allegation by Genentech that Celltrion Inc.'s document productions pursuant to 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(*l*)(3)(B) were deficient, Celltrion Inc. produced substantially more documentation than was required by the statute, and Genentech had in its possession all the information it needed to determine whether Celltrion's Herzuma® product would infringe Genentech's (3)(A) patents.

45. In Celltrion Inc. 's (3)(B) statement, it also stated in accordance with [redacted]. Therefore, Celltrion Inc.'s (3)(B) statement provided detailed statements regarding non-infringement, unenforceability, and/or invalidity for 38 of the 40 patents on Genentech's (3)(A) list.

46. On January 5, 2018, Celltrion Inc. received Genentech's alleged statement pursuant to § 262(*l*)(3)(C) (Genentech's "(3)(C) statement"). Even though the BPCIA required Genentech to provide, among other things, "on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that [each] patent [identified in Celltrion Inc.'s (3)(B) statement] will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application," and a response to Celltrion Inc.'s opinions concerning the validity and enforceability of the listed patents, [redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

47. [redacted]

48. [redacted]

49. On January 11, 2018, Celltrion Inc. wrote to Genentech in response to its (3)(C) statement. Celltrion Inc. stated that, pursuant to 42 U.S.C. § 262(*l*)(4)(A), Celltrion Inc. wished to litigate all of the patents on Genentech's (3)(A) list.

50. [redacted], Celltrion Inc. also notified Genentech that, pursuant to 42 U.S.C. §262(l)(8)(A), Celltrion Inc. was providing notice that commercial marketing of Herzuma® may begin as early as 180 days from the date of the notice.

THE PATENTS-IN-SUIT

51. U.S. Patent No. 6,331,415 (Exhibit 1), titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells For Use Therein," issued on December 18, 2001. Upon information and belief, the '415 patent is assigned to Genentech, Inc. and City of Hope.

52. U.S. Patent No. 6,339,142 (Exhibit 2), titled "Protein Purification" issued on January 15, 2002. Upon information and belief, the '142 patent is assigned to Genentech, Inc.

53. U.S. Patent No. 6,407,213 (Exhibit 3), titled "Method for Making Humanized Antibodies" issued on June 18, 2002. Upon information and belief, the '213 patent is assigned to Genentech, Inc.

54. U.S. Patent No. 6,417,335 (Exhibit 4), titled "Protein Purification," issued on July 9, 2002. Upon information and belief, the '335 patent is assigned to Genentech, Inc.

55. U.S. Patent No. 6,489,447 (Exhibit 5), titled "Protein Purification," issued on December 3, 2002. Upon information and belief, the '447 patent is assigned to Genentech, Inc.

56. U.S. Patent No. 6,586,206 (Exhibit 6), titled "Methods for Making Recombinant Proteins Using Apoptosis Inhibitors," issued on July 1, 2003. Upon information and belief, the '206 patent is assigned to Genentech, Inc.

57. U.S. Patent No. 6,610,516 (Exhibit 7), titled "Cell Culture Process," issued on August 26, 2003. Upon informationa and belief, the '516 patent is assigned to Genentech, Inc.

58. U.S. Patent No. 6,620,918 (Exhibit 8), titled "Separation of Polypeptide Monomers," issued on September 16, 2003. Upon information and belief, the '918 patent is assigned to Genentech, Inc.

59. U.S. Patent No. 6,627,196 (Exhibit 9), titled "Dosages for Treatment with Anti-ErbB2 Antibodies," issued on September 30, 2003. Upon information and belief, the '196 patent is assigned to Genentech, Inc.

60. U.S. Patent No. 6,716,602 (Exhibit 10), titled "Metabolic Rate Shifts in Fermentations Expressing Recombinant Proteins," issued on April 6, 2004. Upon information and belief, the '602 patent is assigned to Genentech, Inc.

61. U.S. Patent No. 7,371,379 (Exhibit 11), titled "Dosages for Treatment with Anti-ErbB2 Antibodies," issued on May 13, 2008. Upon information and belief, the '379 patent is assigned to Genentech, Inc.

62. U.S. Patent No. 7,390,660 (Exhibit 12), titled "Methods for Growing Mammalian Cells In Vitro," issued on June 24, 2008. Upon information and belief, the '660 patent is assigned to Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole right to enforce the '660 patent.

63. U.S. Patent No. 7,449,184 (Exhibit 13), titled "Fixed Dosing of HER Antibodies," issued on November 11, 2008. Upon information and belief, the '184 patent is assigned to Genentech, Inc.

64. U.S. Patent No. 7,485,704 (Exhibit 14), titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," issued on February 3, 2009. Upon information and belief, the '704 patent is assigned to Genentech, Inc.

65. U.S. Patent No. 7,501,122 (Exhibit 15), titled "Treatment With Anti-ErbB2 Antibody Combinations" issued on March 10, 2009. Upon information and belief, the '122 patent is assigned to Genentech, Inc.

66. U.S. Patent No. 7,807,799 (Exhibit 16), titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," issued on October 5, 2010. Upon information and belief, the '799 patent is assigned to Genentech, Inc.

67. U.S. Patent No. 7,846,441 (Exhibit 17), titled "Treatment with Anti-ErbB2 Antibodies," issued on December 7, 2010. Upon information and belief, the '441 patent is assigned to Genentech, Inc.

68. U.S. Patent No. 7,892,549 (Exhibit 18), titled "Treatment with Anti-ErbB2 Antibodies," issued on February 22, 2011. Upon information and belief, the '549 patent is assigned to Genentech, Inc.

69. U.S. Patent No. 7,923,221 (Exhibit 19), titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," issued on April 12, 2011. Upon information and belief, the '221 patent is assigned to Genentech, Inc. and City of Hope.

70. U.S. Patent No. 7,993,834 (Exhibit 20), titled "Detection of ErbB2 Gene Amplification to Increase the Likelihood of the effectiveness of ErbB2 AntiBody Breast Cancer Therapy," issued on August 9, 2011. Upon information and belief, the '834 patent is assigned to Genentech, Inc.

71. U.S. Patent No. 8,076,066 (Exhibit 21), titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," issued on December 13, 2011. Upon information and belief, the '066 patent is assigned to Genentech Inc.

72. U.S. Patent No. 8,357,301 (Exhibit 22), titled "Chromatography Equipment Characterization," issued on January 22, 2013. Upon information and belief, the '301 patent is assigned to Hoffman-La Roche, Inc. Upon information and belief, one or more of the Defendants has the entire right, interest, and title to enforce the '301 patent.

73. U.S. Patent No. 8,425,908 (Exhibit 23), titled "Treatment with Anti-ErbB2 Antibodies," issued on April 23, 2013. Upon information and belief, the '301 patent is assigned to Genentech, Inc.

74. U.S. Patent No. 8,440,402 (Exhibit 24), titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," issued on May 14, 2013. Upon information and belief, the '402 patent is assigned to Genentech, Inc.

75. U.S. Patent No. 8,460,895 (Exhibit 25), titled "Method for Producing Recombinant Proteins with a Constant Content of pCO2 in the Medium," issued on June 11, 2013. Upon information and belief, the '895 patent is assigned to Hoffmann-La Roche, and Genentech is the exclusive licensee with the sole right to enforce the '895 patent.

76. U.S. Patent No. 8,512,983 (Exhibit 26), titled "Production of Proteins in Glutamine-Free Cell Culture Media," issued on August 20, 2013. Upon information and belief, Genentech is the owner of all right, title and interest in the '983 patent.

77. U.S. Patent No. 8,574,869 (Exhibit 27), titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," issued on November 5, 2013. Upon information and belief, the '869 patent is assigned to Genentech, Inc.

78. U.S. Patent No. 8,633,302 (Exhibit 28), titled "Variable Tangential Flow Filtration," issued on January 21, 2014. Upon information and belief, the '302 patent is assigned to Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole right to enforce the '302 patent.

79. U.S. Patent No. 8,691,232 (Exhibit 29), titled "Extending Time to Disease Progression or Survival in Cancer Patients," issued on April 8, 2014. Upon information and belief, the '232 patent is assigned to Genentech, Inc.

80. U.S. Patent No. 8,771,988 (Exhibit 30), titled "Protein expression from multiple nucleic acids," issued on June 24, 2008. Upon information and belief, the '988 patent is assigned to Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole right to enforce the '988 patent.

81. U.S. Patent No. 8,822,655 (Exhibit 31), titled "Pre-filtration adjustment of buffer solutes," issued on September 2, 2014. Upon information and belief, the '655 patent is assigned to

Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole right to enforce the ’655 patent.

82. U.S. Patent No. 9,047,438 (Exhibit 32), titled “Chromatography Equipment Characterization,” issued on June 2, 2015. Upon information and belief, the ’438 patent is assigned to Hoffmann-La Roche.

83. U.S. Patent No. 9,080,183 (Exhibit 33), titled “Promoter,” issued on July 14, 2015. Upon information and belief, the ’183 patent is assigned to Hoffmannn-La Roche Inc.

84. U.S. Patent No. 9,249,218 (Exhibit 34), titled “Protein Purification,” issued on February 2, 2016. Upon information and belief, the ’218 patent is assigned to Genentech, Inc.

85. U.S. Patent No. 9,428,548 (Exhibit 35), titled “Enhanced Protein Purification through a Modified Protein A Elution,” issued on August 30, 2016. Upon information and belief, the ’548 patent is assigned to Genentech, Inc.

86. U.S. Patent No. 9,428,766 (Exhibit 36), titled “Protein expression from multiple nucleic acids,” issued on August 30, 2016. Upon information and belief, the ’766 patent is assigned to Hoffmann-La Roche, Inc. and Genentech, Inc. is the exclusive licensee with the sole right to enforce the ’766 patent.

87. U.S. Patent No. 9,487,809 (Exhibit 37), titled “Decreasing Lactate Level and Increasing Polypeptide Production by Downregulating the Expression of Lactate Dehydrogenase and Pyruvate Dehydrogenase Kinase,” issued on November 8, 2016. Upon information and belief, the ’809 patent is assigned to Genentech, Inc.

88. U.S. Patent No. 9,714,293 (Exhibit 38), titled “Production of Proteins in Glutamine-Free Cell Culture Media,” issued on July 25, 2017. Upon information and belief, the ’293 patent is assigned to Genentech Inc.

COUNT I

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,331,415

89. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-88 above as if fully set forth herein.

90. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '415 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

91. For example, Plaintiffs will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(g) because [redacted]

92. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '415 patent include: [redacted] required by certain claims of the '415 patent.

93. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '415 patent.

94. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

95. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '415 patent.

COUNT II

Declaratory Judgment of Invalidity of U.S. Patent No. 6,331,415

96. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-95 above as if fully set forth herein.

97. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '415 patent are invalid.

98. Non-limiting examples of how one or more claims of the '415 patent are invalid include: (1) lack of enablement of the claimed "process for producing an immunoglobulin molecule," to the extent it encompasses both *in vivo* and *in vitro* assembly, because there is no disclosure in the specification of how to produce an antibody *in vivo* in an microorganism or host cell, and undue experimentation would have been required for a POSA to do so; (2) failure of written description to describe any process for the *in vivo* assembly of an antibody or antibody fragment in either amicroorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include immunoglobins (with heavy and light chains) in a single host cell using a plasmid containing genes. In addition, one or more claims of the '415 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '415 patent.

99. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '415 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

100. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

101. Plaintiffs are entitled to a judicial declaration that one or more claims of the '415 patent are invalid.

COUNT III

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,339,142

102. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-101 above as if fully set forth herein.

103. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '142 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

104. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '142 patent include: [redacted]

105. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '142 patent.

106. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

107. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '142 patent.

COUNT IV

Declaratory Judgment of Invalidity of U.S. Patent No. 6,339,142

108. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-107 above as if fully set forth herein.

109. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '142 patent are invalid.

110. Non-limiting examples of how one or more claims of the '142 patent are invalid include: (1) anticipation by prior art which expressly discloses a composition of trastuzumab and at most about 18% acidic variants thereof and a pharmaceutically acceptable carrier; (2) obviousness

in view of prior art disclosing reasons and methods for separating native trastuzumab from deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical composition to less than about 25%.

111. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '142 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

112. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

113. Plaintiffs are entitled to a judicial declaration that one or more claims of the '142 patent are invalid.

COUNT V

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,407,213

114. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-113 above as if fully set forth herein.

115. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '213 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

116. Plaintiffs will not infringe one or more valid claims of the '213 patent at least because the CT-P6 product [redacted]

117. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '213 patent.

118. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

119. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’213 patent.

COUNT VI

Declaratory Judgment of Invalidity of U.S. Patent No. 6,407,213

120. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-119 above as if fully set forth herein.

121. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.’s opinion that one or more claims of the ’213 patent are invalid.

122. Non-limiting examples of how one or more claims of the ’213 patent are invalid include: 1) anticipation by prior art references teaching substitutions using the Kabat numbering system at sites recited in the ’213 patent claims; 2) anticipation by prior art references teaching the structual components recited in the ’213 patent claims; 3) obviousness in view of prior art disclosing detailed roadmaps for substitutions in antibody sequences to humanize non-human monoclonal antibodies; 4) indefiniteness because claim terms such as “consensus human variable domain” and “the most frequently occurring amino acid residues at each location in all human immunoglobulins” can have multiple definitions; 5) lack of adequate written description because “comprising non-human Complementarity Determining Region (CDR) amino acid residues which bind an antigen” would require substantial mapping and binding studies not disclosed in the ’213 patent specification; and 6) obviousness-type double patenting over claims of U.S. Patent No. 5,821,337.

123. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the ’213 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

124. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

125. Plaintiffs are entitled to a judicial declaration that one or more claims of the '213 patent are invalid.

COUNT VII

Declaratory Judgment of Unenforceability of U.S. Patent No. 6,407,213

126. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-125 above as if fully set forth herein. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that the '213 patent is unenforceable.

127. During the prosecution of the '213 patent, Genentech made misrepresentations and omissions material to patentability and did so with the specific intent to mislead or deceive the Patent Office and with knowledge that the misrepresentations were material to patentability.

128. Genentech deliberately misrepresented the teachings of U.S. Patent No. 5,530,101 ("'101 patent") to the Patent Office in order to overcome a rejection based on that reference. Specifically, Genentech told the Examiner that the '101 patent does not use the Kabat numbering system, despite its repeated references to "numbering according to Kabat" and "the Kabat system."

129. Genentech also made deliberate misrepresentations and omissions regarding Queen *et al.*, *A Humanized Antibody that Binds to the Interleukin 2 Receptor*, PRO. NAT'L ACAD. SCI. 86:10029–33 (1989) ("Queen 1989"), including (i) falsely distinguishing Queen 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering system; and (ii) providing information at the request of the Examiner that conspicuously omitted a key residue ("62L") disclosed in the prior art. Deceptive intent by Genentech is the single most reasonable inference to be drawn from the prosecution history and all other available evidence.

130. On November 17, 1993, Genentech filed its patent application with claims requiring substitutions selected from a set of specific locations, including positions "62L" and

"93H." On December 9, 1994, the Examiner issued a Non-Final Rejection, rejecting the claims as obvious under § 103 over EP 0239400, Queen 1989, Riechmann 1988.

131. On June 12, 1995, Genentech amended the pending claims and deleted references to amino acid position "62L."

132. Following a final rejection and an Examiner interview, the case was transferred to a different Examiner and a new non-final rejection issued on December 23, 1996. The new Examiner maintained all prior rejections and further rejected the pending claims as anticipated by the '101 patent.

133. In response to the non-final rejection, Genentech once again amended the pending claims on June 27, 1997, adding amino acid position "62L" back into the claims.

134. On October 7, 1997, in a letter signed by Wendy M. Lee on behalf of Genentech, Genentech argued in remarks to the Patent Office that Queen 1989 and the '101 patent were distinguishable because they "use sequential numbering for the variable domain residues of the antibodies described in these references, whereas the claims of the instant application use Kabat numbering for the framework region residues." In another submission by Wendy M. Lee on behalf of Genentech later in the prosecution of the '213 patent, Genentech repeated the same argument to distinguish Queen 1989 and the '101 patent with specific reference to residue "93H":

> Applicants point out that – as explained earlier in prosecution – the substituted 93 FR residue in the cited references [Queen 1989 and the '101 patent] is not 93H 'utilizing the numbering system set forth in Kabat' (see page 13, line 33 through to line 22 on page 14 of the present application) as required by claims 115-117, 123 and 127 of the present application. In particular, as noted on page 6 of the amendment hand carried to the Office on 10/7/97, residue no. 93 in the heavy chain of the anti-Tac antibody in the cited references, is actually 89H utilizing the numbering system set forth in Kabat. The cited

> references use a sequential numbering system, rather than the Kabat numbering system claimed herein.

See Applicant Remarks, dated Apr. 26, 2001, at 7.

135. On December 11, 2001, the Examiner indicated during an interview that the pending claims were allowable.

136. Contrary to Genentech's representations to the Patent Office—namely, that the '101 patent does not use the Kabat numbering system—the '101 patent states: "Residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest (National Institutes of Health, Bethesda, Md.) (1987)." '101 patent at 8:15–18. In addition, the '101 patent expressly refers to "numbering according to Kabat, op. cit." with specific reference to position 93 in the heavy chain. *See id.* at 15:17–37. Moreover, Table 5 of the '101 patent refers to residue "H93," with explicit reference to numbering "according to the Kabat system," as shown below:

TABLE 5

Residues in the framework sequence showing contacts with residues in the hypervariable regions.

Residue No.[1]	Amino Acid	Contacting CDR residues[2]
Fd79		
L49	Lys	L50Y, L53N, L55E, H99D, H100Y
H93	Leu	H35S, H37V, H100CF
Fd138-80		
L36	His	L34V, L89Q
H27	Tyr	H32H, H34I
H30	Tyr	H32H, H53R
H48	Phe	H63F
H66	Lys	H63F
H67	Ala	H63F

1. The amino acid residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest, National Institutes of Health, Bethesda, MD (1987)): the first letter (H or L) stands for the heavy chain or light chain. The following number is the residue number. The last letter is the amino acid one letter code.
2. The hypervariable regions are defined according to Kabat: Light chain CDR1: residue 24–34; CDR2: 50–56; CDR3: 89–97. Heavy chain CDR1: 31–35; CDR2: 50–65; CDR3: 95–102.

137. In order to overcome the § 102 rejection based on the '101 patent, Genentech falsely represented to the Patent Office that the '101 patent used sequential numbering, while arguing that the "claims of the instant application use Kabat numbering for the framework region residues." Genentech misrepresented the teachings of the '101 patent, despite clear and repeated references in the '101 patent to the Kabat numbering system. Absent Genentech's false and

misleading distinction, the Examiner had no reason to withdraw the § 102 rejection based on the '101 patent. But-for Genentech's misrepresentations, the Patent Office would not have allowed the claims of the '213 patent.

138. Genentech also made deliberate and material misrepresentations and omissions regarding Queen 1989 during the prosecution of the '213 patent. Genentech distinguished Queen 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering system. At the Examiner's request, Genentech submitted a comparison of the different numbering systems purportedly utilized in Queen 1989 and the pending claims. *See* Applicant Remarks at 6–10 (Oct. 7, 2997) ("As requested by the Examiner in the interview, alignments of heavy chain variable domain (Exhibit A) and light chain variable domain (Exhibit B) sequences of the 101 patent (including the sequences for the murine and humanized anti-Tac antibody of Queen et al.) with sequential andKabat residue numbering is attached."). The alignments provided by Genentech to the Examiner conspicuously omitted the "62L" residue in both numbering systems. As noted above, residue "62L" was recited in then-pending claims of the '213 patent, and Queen 1989 expressly discloses "residues at positions corresponding to . . . 47 and 62 of the light chain (Fig. 2)." *See* Queen 1989 at 10032. Importantly, Queen 1989 discloses residues in the Kabat numbering system and, in particular, residue "62 of the light chain."

139. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether the claims of the '213 patent are enforceable.

140. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

141. Plaintiffs are entitled to a judicial declaration that the '213 patent is unenforceable.

COUNT VIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,417,335

142. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-141 above as if fully set forth herein.

143. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '335 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

144. For example, Plaintiffs will not infringe one or more claims of the '335 patent under 35 U.S.C. § 271(a) [redacted]. Plaintiffs also will not infringe one or more claims of the '335 patent under 35 U.S.C. § 271(g) because [redacted]

145. An additional non-limiting example of how Plaintiffs will not infringe any valid claim of the '335 patent is that [redacted]

146. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '335 patent.

147. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

148. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '335 patent.

COUNT IX

Declaratory Judgment of Invalidity of U.S. Patent No. 6,417,335

149. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-148 above as if fully set forth herein.

150. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '335 patent are invalid.

151. One or more claims of the '335 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '335 patent. Non-limiting examples of how one or more claims of the '335 patent are invalid include: (1) anticipation in view of the prior art disclosing each and every limitation of claim 1 of the '335 patent regarding "purifying" of "an antibody from a composition comprising the antibody and a contaminant" by "loading the composition onto a cation exchange resin" and "eluting the contaminant from the cation exchange resin"; and (2) obviousness in view of prior art disclosing the purification of an antibody by loading that antibody onto a cation exchange resin.

152. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '335 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

153. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

154. Plaintiffs are entitled to a judicial declaration that one or more claims of the '335 patent are invalid.

COUNT X

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,489,447

155. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-154 above as if fully set forth herein.

156. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '447 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

157. For example, Plaintiffs will not infringe one or more claims of the '447 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '447 patent under 35 U.S.C. § 271(g) because [redacted]

158. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '447 patent include that [redacted]

159. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '447 patent.

160. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

161. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '447 patent.

COUNT XI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,586,206

162. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-161 above as if fully set forth herein.

163. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion

Inc.'s opinion that one or more claims of the '206 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

164. For example, Plaintiffs will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(g) because [redacted]

165. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '206 patent include [redacted]

166. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '206 patent.

167. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

168. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '206 patent.

COUNT XII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,610,516

169. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-168 above as if fully set forth herein.

170. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '516 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

171. For example, Plaintiffs will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(a) [redacted] Plaintiffs also will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(g) because [redacted]

172. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '516 patent include: [redacted]

173. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '516 patent.

174. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

175. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '516 patent.

COUNT XIII

Declaratory Judgment of Invalidity of U.S. Patent No. 6,610,516

176. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-175 above as if fully set forth herein.

177. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '516 patent are invalid.

178. Non-limiting examples of how one or more claims of the '516 patent are invalid include: (1) anticipation by prior art disclosing processes for increasing the percentage of a human glycoprotein having one glycoform by producing the glycoproteins in CHO cells in the presence of about 0 to 2 mM of a butyrate salts at a temperature of about 30° C to 35° C, and inherently and/or expressly disclosing all limitations of the claim of the '516 patent; (2) obviousness in view of prior art disclosing producing human glycoproteins with increased abundance of particular glycoforms by including butyrate salts in the media and/or controlling the temperature of the culture in the range of 30° C. to 35° C, and (3) to the extent not obvious, lack of enablement of the claimed "process for producing a human glycoprotein having multiple glycoforms" with "an increased percentage of glycoprotein molecules having one glycoform" because there is no disclosure in the specification of how to perform the claimed process to produce glycoproteins other than t-PA, and undue experimentation would have been required for a POSA to do so.

179. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '516 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

180. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

181. Plaintiffs are entitled to a judicial declaration that one or more claims of the '516 patent are invalid.

COUNT XIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,620,918

182. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-181 above as if fully set forth herein.

183. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '918 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

184. For example, Plaintiffs will not infringe one or more claims of the '918 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '918 patent under 35 U.S.C. § 271(g) because [redacted]

185. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '918 patent include [redacted]

186. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '918 patent.

187. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

188. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '918 patent.

COUNT XV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,627,196

189. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-188 above as if fully set forth herein.

190. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '196 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

191. Non-limiting examples of how Plaintiffs will not infringe one or more claims of the '196 patent include: 1) Plaintiffs will not infringe one or more claims of the '196 patent under 35 U.S.C. § 271(a) because Plaintiffs will not treat patients; and (2) Plaintiffs will not infringe one or more claims of the '196 patent under 35 U.S.C. §§ 271(b) or (c) at least because Plaintiffs will not encourage another party to practice the claimed methods because [redacted]

192. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '196 patent.

193. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

194. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '196 patent.

COUNT XVI

Declaratory Judgment of Invalidity of U.S. Patent No. 6,627,196

195. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-194 above as if fully set forth herein.

196. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '196 patent are invalid.

197. Non-limiting examples of how one or more claims of the '196 patent are invalid include: 1) obviousness in view of prior art disclosing a motivation to pursue a less frequent dosing regimen, and the safety and efficacy of the claimed dosing regimen of the '196 patent; and 2) to the extent Genentech argues that the person of ordinary skill in the art would not have expected that administration of trastuzumab less frequently than the half-life reported in the prior art to be successful without knowledge of its purportedly longer half-life, lack of enablement.

198. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '196 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

199. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

200. Plaintiffs are entitled to a judicial declaration that one or more claims of the '196 patent are invalid.

COUNT XVII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,716,602

201. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-200 above as if fully set forth herein.

202. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '602 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

203. For example, Plaintiffs will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(a) because [redacted]

Plaintiffs also will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(g) because [redacted]

204. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '602 patent include: [redacted]

205. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '602 patent.

206. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

207. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '602 patent.

COUNT XVIII

Declaratory Judgment of Invalidity of U.S. Patent No. 6,716,602

208. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-207 above as if fully set forth herein.

209. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '602 patent are invalid.

210. Non-limiting examples of how one or more claims of the '602 patent are invalid include: (1) lack of enablement of the claimed "method for increasing product yield of a properly folded polypeptide," to the extent it encompasses production of protein in host cells other than

prokaryotic and simple eukaryotic systems, because there is no disclosure in the specification of how to practice the invention in any complex eukaryotic system such as a CHO cell; and (2) lack of written description because the specification does not describe increasing the yield of a properly folded polypeptide in any expression system other than prokaryotic and simple eukaryotic systems. In addition, one or more claims of the '602 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '602 patent.

211. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '602 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

212. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

213. Plaintiffs are entitled to a judicial declaration that one or more claims of the '602 patent are invalid.

COUNT XIX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,371,379

214. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-213 above as if fully set forth herein.

215. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '379 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

216. Non-limiting examples of how Plaintiffs will not infringe one or more claims of the '379 patent include: 1) Plaintiffs will not infringe one or more claims of the '379 patent under 35 U.S.C. § 271(a) because Plaintiffs will not treat patients; and (2) Plaintiffs also will not infringe one or more claims of the '379 patent under 35 U.S.C. §§ 271(b) or (c) at least because Plaintiffs will not encourage another party to practice the claimed methods because [redacted]

[redacted]

217. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '379 patent.

218. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

219. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '379 patent.

COUNT XX

Declaratory Judgment of Invalidity of U.S. Patent No. 7,371,379

220. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-219 above as if fully set forth herein.

221. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '379 patent are invalid.

222. Non-limiting examples of how one or more claims of the '379 patent are invalid include: 1) obviousness in view of prior art disclosing a motivation to pursue a less frequent dosing regimen, and the safety and efficacy of the claimed dosing regimen of the '379 patent; 2) to the extent Genentech argues that the person of ordinary skill in the art would not have expected that administration of trastuzumab less frequently than the half-life reported in the prior art to be successful without knowledge of its purportedly longer half-life, lack of enablement; and 3) indefiniteness because claim terms such as "the sum of the effective amounts" can have multiple definitions.

223. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '379 patent are invalid for failure to

comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

224. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

225. Plaintiffs are entitled to a judicial declaration that one or more claims of the '379 patent are invalid.

COUNT XXI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,390,660

226. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-225 above as if fully set forth herein.

227. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '660 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

228. For example, Plaintiffs will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(g) because [redacted]

229. Additional non-limiting examples of how Plaintiffs will not infringe any valid claim of the '660 patent include that [redacted]

230. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '660 patent.

231. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

232. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '660 patent.

COUNT XXII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,449,184

233. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-232 above as if fully set forth herein.

234. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '184 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

235. For example, Plaintiffs will not directly infringe any claim of the '184 patent because all the claims are all directed to methods of treating patients and Plaintiffs will not treat patients. Plaintiffs will also not induce infringement because [redacted]

236. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '184 patent.

237. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

238. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '184 patent.

COUNT XXIII

Declaratory Judgment of Invalidity of U.S. Patent No. 7,449,184

239. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-238 above as if fully set forth herein.

240. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '184 patent are invalid.

241. Non-limiting examples of how one or more claims of '184 patent are invalid is because the claims are invalid under 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious over the prior art, including at least U.S. App. 10/619,754, Canadian Patent Application 2,376,596, WO01000245 and prior art that describes a phase 1b study demonstrating the efficacy of the combination of pertuzumab and capecitabine, the fixed doses of the claims, and disclosing or suggesting the other elements of the claims.

242. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '184 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

243. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

244. Plaintiffs are entitled to a judicial declaration that claims of the '184 patent are invalid.

COUNT XXIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,485,704

245. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-244 above as if fully set forth herein.

246. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '704 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

247. For example, Plaintiffs will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(g) because [redacted]

248. An additional, non-limiting example of how Plaintiffs will not infringe one or more valid claims of the '704 patent is that [redacted]

249. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendatnts concerning whether Plaintiffs will infringe any valid and enforceable claim of the '704 patent.

250. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

251. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '704 patent.

COUNT XXV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,501,122

252. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-251 above as if fully set forth herein.

253. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '122 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

254. For example, Plaintiffs will not directly infringe any claim of the '122 patent because all the claims are all directed to methods of treating patients and Plaintiffs will not treat patients. Plaintiffs will also not induce infringement because [redacted]

255. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '122 patent.

256. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

257. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '122 patent.

COUNT XXVI

Declaratory Judgment of Invalidity of U.S. Patent No. 7,501,122

258. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-257 above as if fully set forth herein.

259. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '122 patent are invalid.

260. A non-limiting example of how one or more claims of the '122 patent are invalid is because the claims are invalid under 35 U.S.C. § 103 as obvious over the prior art, including at least the original prescribing information for HERCEPTIN® and prior art disclosing that humanized 2C4 antibody and HERCEPTIN® bind to different ErbB2 epitopes and suggesting their additive therapeutic effect when combined or coadministered.

261. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '122 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

262. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

263. Plaintiffs are entitled to a judicial declaration that one or more claims of the '122 patent are invalid.

COUNT XXVII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,807,799

264. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-263 above as if fully set forth herein.

265. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '799 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

266. For example, Plaintiffs will not infringe one or more claims of the '799 patent under 35 U.S.C. § 271(a) because [redacted]. Plaintiffs also will not infringe one or more claims of the '799 patent under 35 U.S.C. §

271(g) because [redacted]

267. An additional, non-limiting example of how Plaintiffs will not infringe one or more valid claims of the '799 patent is that [redacted]

268. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '799 patent.

269. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

270. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '799 patent.

COUNT XXVIII

Declaratory Judgment of Invalidity of U.S. Patent No. 7,807,799

271. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-270 above as if fully set forth herein.

272. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '799 patent are invalid.

273. For example, one or more claims of the '799 patent are invalid as anticipated or obvious in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '799 patent, including prior art that disclosed carrying out the claimed methods at room temperature of 18°C to 25°C.

274. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '799 patent are invalid for failure to

comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

275. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

276. Plaintiffs are entitled to a judicial declaration that one or more claims of the '799 patent are invalid.

COUNT XXIX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,846,441

277. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-276 above as if fully set forth herein.

278. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '441 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

279. For example, Plaintiffs will not directly infringe any claim of the '441 patent because all the claims are directed to methods of treating patients, and Plaintiffs will not treat patients. Plaintiffs will also not induce infringement because [redacted] In addition, there are substantial noninfringing uses for CT-P6. [redacted]

280. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '441 patent.

281. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

282. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '441 patent.

COUNT XXX

Declaratory Judgment of Invalidity of U.S. Patent No. 7,846,441

283. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-282 above as if fully set forth herein.

284. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '441 patent are invalid.

285. Non-limiting examples of how one or more claims of the '441 patent are invalid include: 1) obviousness over prior art that establishes a motivation to use the claimed combinantion, and the safety and efficacy of the same; 2) indefiniteness because claim terms such as "an amount effective to extend the time to disease progression without increase in overall severe adverse events" and "sum of the effective amounts" can have multiple definitions; and 3) lack of written description because, to the extent the claim limitation can be understood, the specification does not demonstrate possession of the claim limitation "without increase in overall severe adverse events."

286. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '441 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

287. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

288. Plaintiffs are entitled to a judicial declaration that one or more claims of the '441 patent are invalid.

COUNT XXXI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,892,549

289. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-288 above as if fully set forth herein.

290. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '549 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

291. For example, Plaintiffs will not directly infringe any claim of the '549 patent because all the claims are all directed to methods of treating patients and Plaintiffs will not treat patients.

292. Plaintiffs will not induce infringement of the '549 patent claims because, for example,

293. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '549 patent.

294. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

295. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '549 patent.

COUNT XXXII

Declaratory Judgment of Invalidity of U.S. Patent No. 7,892,549

296. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-295 above as if fully set forth herein.

297. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '549 patent are invalid.

298. Non-limiting examples of how one or more claims of the '549 patent are invalid include: 1) obviousness over prior art that establishes a motivation to use the claimed combinantion, and the safety and efficacy of the same; 2) lack of enablement and written description with respect to the claimed further "growth inhibitory" or "therapeutic" agent; 3) and indefiniteness because claim terms such as "an amount effective to extend the time to disease progression" can have multiple definitions.

299. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '549 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

300. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

301. Plaintiffs are entitled to a judicial declaration that one or more claims of the '549 patent are invalid.

COUNT XXXIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,923,221

302. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-301 above as if fully set forth herein.

303. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '221 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

304. For example, Plaintiffs will not infringe one or more claims of the '221 patent under 35 U.S.C. § 271(a) because [redacted]. Plaintiffs also will not infringe one or more claims of the '221 patent under 35 U.S.C. § 271(g) because [redacted]

305. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '221 patent include: [redacted]

306. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '221 patent.

307. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

308. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’221 patent.

COUNT XXXIV

Declaratory Judgment of Invalidity of U.S. Patent No. 7,923,221

309. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-308 above as if fully set forth herein.

310. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.’s opinion that one or more claims of ’221 patent are invalid.

311. Non-limiting examples of how one or more claims of the ’221 patent are invalid include: (1) lack of enablement of the claimed “process for producing an immunoglobulin molecule,” to the extent it encompasses both *in vivo* and *in vitro* assembly, because there is no disclosure in the specification of how to produce an antibody *in vivo* in an microorganism or host cell, and undue experimentation would have been required for a POSA to do so; (2) failure of written description to describe any process for the *in vivo* assembly of an antibody or antibody fragment in either amicroorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include immunoglobins (with heavy and light chains) in a single host cell using a plasmid containing genes. In addition, one or more claims of the ’221 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the ‘221 patent.

312. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendatns concerning whether one or more claims of the ’221 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

313. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

314. Plaintiffs are entitled to a judicial declaration that one or more claims of the '221 patent are invalid.

COUNT XXXV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,993,834

315. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-314 above as if fully set forth herein.

316. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '834 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

317. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '834 patent include: (1) Plaintiffs cannot be liable for direct infringement of the claimed method because Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; [redacted]; (3) in the patent specification and during prosecution of the patent, the patentees expressly disclaimed [redacted] and (4) the patent specification itself acknowledges there are substantial non-infringing uses for Celltrion's CT-P6 product, and [redacted].

318. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '834 patent.

319. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

320. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’834 patent.

COUNT XXXVI

Declaratory Judgment of Invalidity of U.S. Patent No. 7,993,834

321. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-320 above as if fully set forth herein.

322. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.’s opinion that one or more claims of the ’834 patent are invalid.

323. Non-limiting examples of how one or more claims of the ’834 patent are invalid include: (1) the claims are indefinite because they fail to identify a baseline likelihood of effectiveness from which the meaning of the claimed method can be ascertained; (2) the claims are invalid for lack of written description because the patent fails to disclose any data or information to support the claimed correlations between test results and treatment; (3) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural correlation between known diagnostic tests and responses rates to a known method of treatment; (4) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; (5) the claims are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

324. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the ’834 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

325. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

326. Plaintiffs are entitled to a judicial declaration that one or more claims of the '834 patent are invalid.

COUNT XXXVII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,076,066

327. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-326 above as if fully set forth herein.

328. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '066 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

329. Non-limiting examples of how Plaintiffs will not infringe one or more valid claim of the '066 patent include: (1) Plaintiffs cannot be liable for direct infringement of the claimed method because Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; (2) [redacted] (3) in the patent specification and during prosecution of the patent, the patentees expressly disclaimed [redacted]; and (4) the patent specification itself acknowledges there are substantial non-infringing uses for Celltrion's CT-P6 product, and [redacted]

330. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '066 patent.

331. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

332. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '066 patent.

COUNT XXXVIII

Declaratory Judgment of Invalidity of U.S. Patent No. 8,076,066

333. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-332 above as if fully set forth herein.

334. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that the '066 patent is invalid.

335. Non-limiting examples of how the '066 patent is invalid include: (1) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural law relating known biomarkers to known disposition to respond to treatment with trastuzumab; (2) the claims are invalid for lack of written description because the patent fails to show a direct correlation between treatment responsiveness and IHC scores of 0/1+; (3) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; and (4) claims 2-3, 5-6 are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

336. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether the claims of the '066 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

337. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

338. Plaintiffs are entitled to a judicial declaration that all claims of the '066 patent are invalid.

COUNT XXXIX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,357,301

339. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-338 above as if fully set forth herein.

340. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '301 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

341. For example, Plaintiffs will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(g) because [redacted]

342. Additional, non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '301 patent include because [redacted]

343. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '301 patent.

344. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

345. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '301 patent.

COUNT XL

Declaratory Judgment of Invalidity of U.S. Patent No. 8,357,301

346. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-345 above as if fully set forth herein.

347. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '301 patent are invalid.

348. A non-limiting example of how one or more claims of the '301 patent are invalid include that the claims of the '301 patent, which recite methods for using a mathematical formula to determine whether a re-usable chromatography column packing has reduced separation efficacy when used at least for the second time in a purification of a polypeptide, are directed essentially to a method of calculating, using a mathematical formula, an inert change of a property of the chromatography material, and thus are invalid as unpatentable subject matter under 35 U.S.C. § 101.

349. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '301 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

350. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

351. Plaintiffs are entitled to a judicial declaration that one or more claims of the '301 patent are invalid.

COUNT XLI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,425,908

352. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-351 above as if fully set forth herein.

353. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '908 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

354. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '908 patent include: (1) Plaintiffs cannot be liable for direct infringement of the claimed methods because Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; (2) Plaintiffs cannot be liable for induced infringement because [redacted]

355. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '908 patent.

356. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

357. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '908 patent.

COUNT XLII

Declaratory Judgment of Invalidity of U.S. Patent No. 8,425,908

358. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-357 above as if fully set forth herein.

359. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '908 patent are invalid.

360. Non-limiting examples of how one or more claims of the '908 patent are invalid include because the claims are invalid as obvious in view of the prior art, including at least Tokuda et al., In Vitro and In Vivo Anti-Tumour Effects of a Humanised Monoclonal Antibody Against c-erbB-2 Product, 73 BRITISH J. CANCER 1362-1365 (1996); A. Hendlisz et al., Diagnosis and Treatment of Gastric Cancer, 49(5) DRUGS 711-720 (1995) and M. Pegram et al., Phase II Study of Intravenous Recombinant Humanized Anti-p185 HER-2 Monoclonal Antibody (rhuMAB HER-2) Plus Cisplatin in Patients with HER-2/NEU Overexpressing Metastatic Breast Cancer, 14 PROC. AM. SOC'Y CLIN. ONCOLOGY 106, abs. 124.

361. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '908 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

362. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

363. Plaintiffs are entitled to a judicial declaration that one or more claims of the '908 patent are invalid.

COUNT XLIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,440,402

364. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-363 above as if fully set forth herein.

365. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '402 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

366. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '402 patent include: (1) Plaintiffs will not be liable for direct infringement of the claimed method because Plaintiffs will not use or directly treat patients with CT-P6 and therefore will not practice any of the claimed methods; [redacted]; (3) in the patent specification and during prosecution of the patent, the patentees expressly disclaimed t[redacted] and (4) the patent specification itself acknowledges there are substantial non-infringing uses for the CT-P6 product, a[redacted]

367. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '402 patent.

368. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

369. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '402 patent.

COUNT XLIV

Declaratory Judgment of Invalidity of U.S. Patent No. 8,440,402

370. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-369 above as if fully set forth herein.

371. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '402 patent are invalid.

372. Non-limiting examples of how one or more claims of the '402 patent are invalid include: (1) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural law relating known biomarkers to known disposition to respond to treatment with trastuzumab; (2) the claims are invalid for lack of written description because the patent fails to show a direct correlation between treatment responsiveness and IHC scores of 0/1+; (3) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; and (4) claims 2-3, 5-6 are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

373. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '402 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

374. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

375. Plaintiffs are entitled to a judicial declaration that one or more claims of the '402 patent are invalid.

COUNT XLV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,460,895

376. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-375 above as if fully set forth herein.

377. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '895 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

378. For example, Plaintiffs will not infringe one or more claims of the '895 patent under 35 U.S.C. § 271(a) because [redacted]. Plaintiffs also will not infringe one or more claims of the '895 patent under 35 U.S.C. § 271(g) because [redacted]

379. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '895 patent include: [redacted].

380. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '895 patent.

381. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

382. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '895 patent.

COUNT XLVI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,512,983

383. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-382 above as if fully set forth herein.

384. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims fo the '983 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

385. For example, Plaintiffs will not infringe one or more claims of the '983 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs will not infringe the product claim of the '983 patent (claim 25) under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '983 patent under 35 U.S.C. § 271(g) because [redacted]

386. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '983 patent include: [redacted]

387. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '983 patent.

388. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

389. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’983 patent.

COUNT XLVII

Declaratory Judgment of Invalidity of U.S. Patent No. 8,512,983

390. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-389 above as if fully set forth herein.

391. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.’s opinion that one or more claims of the ’983 patent are invalid.

392. Non-limiting examples of how one or more claims of the ’983 patent are invalid include: (1) anticipation by prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM and every other claim limitation; and (2) obviousness over prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM, and art disclosing the prodction of therapeuic proteins, including anti-CD20 antibodies, in CHO cells.

393. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the ’983 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

394. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

395. Plaintiffs are entitled to a judicial declaration that one or more claims of the ’983 patent are invalid.

COUNT XLVIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,574,869

396. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-395 above as if fully set forth herein.

397. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '869 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

398. For example, Plaintiffs will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(g) [redacted]

399. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '869 patent include: [redacted]

400. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '869 patent.

401. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

402. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '869 patent.

COUNT XLIX

Declaratory Judgment of Invalidity of U.S. Patent No. 8,574,869

403. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-402 above as if fully set forth herein.

404. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '869 patent are invalid.

405. Non-limiting examples of how one or more claims of the '869 patent are invalid include: (1) lack of written description for the claim term "following fermentation, sparging the pre-harvest or harvested culture fluid" as the patent is slient concering any air sparging of a pre-harvest cell culture fluid, let alone a post-fermentation, pre-harvest solution; and (2) obviousness in view of prior art disclosing processes for methods of preventing the reduction of disulfide bonds via air sparging. In addition, one or more claims of the '869 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '869 patent.

406. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '869 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

407. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

408. Plaintiffs are entitled to a judicial declaration that one or more claims of the '869 patent are invalid.

COUNT L

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,633,302

409. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-408 above as if fully set forth herein.

410. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '302 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

411. For example, Plaintiffs will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(g) because [redacted]

412. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '302 patent include that [redacted]

413. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '302 patent.

414. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

415. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '302 patent.

COUNT LI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,691,232

416. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-415 above as if fully set forth herein.

417. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s

opinion that one or more claims of '232 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

418. For example, Plaintiffs will not directly infringe any claim of the '232 patent because all the claims are all directed to methods of treating patients and Plaintiffs will not treat patients. Plaintiffs will also not induce infringement because [redacted]

419. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '232 patent.

420. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

421. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '232 patent.

COUNT LII

Declaratory Judgment of Invalidity of U.S. Patent No. 8,691,232

422. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-421 above as if fully set forth herein.

423. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '232 patent are invalid.

424. A non-limiting example of how one or more claims of the '232 patent are invalid is because the claims are invalid under 35 U.S.C. § 102 as anticipated by the prior art, including at least U.S. Application No. 10/619,754.

425. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '232 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

426. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

427. Plaintiffs are entitled to a judicial declaration that one or more claims of the '232 patent are invalid.

COUNT LIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,771,988

428. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-427 above as if fully set forth herein.

429. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that the '988 patent would not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

430. For example, Plaintiffs will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(g) because [redacted]

431. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '988 patent include [redacted]

432. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '988 patent.

433. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

434. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '988 patent.

COUNT LIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,822,655

435. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-434 above as if fully set forth herein.

436. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '655 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

437. For example, Plaintiffs will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(g) because [redacted]

438. Additional non-limiting examples of how Plaintiffs will not infringe one or more valids claim of the '655 patent at least because the [redacted]

439. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '655 patent.

440. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

441. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '655 patent.

COUNT LV

Declaratory Judgment of Invalidity of U.S. Patent No. 8,822,655

442. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-441 above as if fully set forth herein.

443. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '655 patent are invalid.

444. Non-limiting examples of how the '655 patent is invalid include a failure to claim patentable subject matter as each claim of the '655 patent is directed towards an abstract idea, including the use of two equations to determine how to adjust a "first concentration" of buffer substance to arrive at "a second concentration" in order to allegedly achieve a more consistent preparation of immunoglobulin after concentration by tangential flow filtration.

445. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '655 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

446. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

447. Plaintiffs are entitled to a judicial declaration that one or more claims of the '655 patent are invalid.

COUNT LVI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,047,438

448. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-447 above as if fully set forth herein.

449. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '438 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

450. For example, Plaintiffs will not infringe any claim of the '438 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '438 patent under 35 U.S.C. § 271(g) because [redacted]

451. Additional, non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '438 patent include that [redacted]

452. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '438 patent.

453. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

454. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '438 patent.

COUNT LVII

Declaratory Judgment of Invalidity of U.S. Patent No. 9,047,438

455. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-454 above as if fully set forth herein.

456. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '438 patent are invalid.

457. A non-limiting example of how one or more claims of the '438 patent are invalid include that the claims of the '438 patent, which recite methods for using a mathematical formula to determine whether a re-usable chromatography column packing has reduced separation efficacy when used at least for the second time in a purification of a polypeptide, are directed essentially to a method of calculating, using a mathematical formula, an inert change of a property of the chromatography material, and thus are invalid as unpatentable subject matter under 35 U.S.C. § 101.

458. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether the claims of the '438 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

459. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

460. Plaintiffs are entitled to a judicial declaration that one or more claims of the '438 patent are invalid.

COUNT LVIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,080,183

461. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-460 above as if fully set forth herein.

462. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '183 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

463. For example, Plaintiffs will not infringe one or more claims of the '183 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '183 patent under 35 U.S.C. § 271(g) because [redacted]

464. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '183 patent include [redacted]

465. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '183 patent.

466. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

467. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '183 patent.

COUNT LIX

Declaratory Judgment of Invalidity of U.S. Patent No. 9,080,183

468. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-467 above as if fully set forth herein.

469. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '183 patent are invalid.

470. Non-limiting examples of how one or more claims of the '183 patent are invalid include obviousness in view of prior art disclosing the use of truncated versions of the SV40 promotor to drive protein expression and art disclosing the use of weaker promotor sequences to improve protein expression. In addition, one or more claims of the '183 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '183 patent.

471. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '183 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

472. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

473. Plaintiffs are entitled to a judicial declaration that one or more claims of the '183 patent are invalid.

COUNT LX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,249,218

474. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-473 above as if fully set forth herein.

475. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '218 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

476. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '218 patent include: [redacted]

[redacted]

477. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the ’218 patent.

478. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

479. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’218 patent.

COUNT LXI

Declaratory Judgment of Invalidity of U.S. Patent No. 9,249,218

480. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-479 above as if fully set forth herein.

481. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.’s opinion that one or more claims of the ’218 patent are invalid.

482. Non-limiting examples of how one or more claims of the ’218 patent are invalid include: (1) anticipation by prior art which expressly disclosed a therapeutic lyophilized composition comprising trastuzumab and at most about 18% acidic variants thereof and a pharmaceutically acceptable carrier, and inherently disclosed any valid remaining limitations; (2) obviousness in view of prior art disclosing reasons and methods for separating native trastuzumab from deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical composition to low levels, including levels of 13%, for pharmaceutical compositions.

483. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendnats concerning whether one or more claims of the ’218 patent are invalid for failure to

comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

484. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

485. Plaintiffs are entitled to a judicial declaration that one or more claims of the '218 patent are invalid.

COUNT LXII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,548

486. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-485 above as if fully set forth herein.

487. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '548 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

488. For example, Plaintiffs will not infringe one or more claims of the '548 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '548 patent under 35 U.S.C. § 271(g) because [redacted]

489. An additional non-limiting example of how Plaintiffs will not infringe one or more valid claims of the '548 patent include that Plaintiffs [redacted]

[redacted]

490. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '548 patent.

491. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

492. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '548 patent.

COUNT LXIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,766

493. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-492 above as if fully set forth herein.

494. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '766 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

495. For example, Plaintiffs will not infringe the sole claim of the '766 patent under 35 U.S.C. § 271(a) because [redacted]

496. Additional non-limiting examples of how Plaintiffs will not infringe the sole claim of the '766 patent include [redacted]

497. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '766 patent.

498. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

499. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '766 patent.

COUNT LXIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,487,809

500. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-499 above as if fully set forth herein.

501. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '809 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

502. For example, Plaintiffs will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(g) because [redacted]

503. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '809 patent include that [redacted]

504. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '809 patent.

505. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

506. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '809 patent.

COUNT LXV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,714,293

507. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-506 above as if fully set forth herein.

508. On November 7, 2017, Celltrion Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion Inc.'s opinion that one or more claims of the '293 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

509. For example, Plaintiffs will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(g) because [redacted]

510. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '293 patent include: [redacted]

[redacted]

511. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '293 patent.

512. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

513. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '293 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against Genentech, Roche, and City of Hope and grant the following relief:

A. Declare that Plaintiffs have not, do not, and will not infringe any valid and enforceable claim of U.S. Patent Nos. 6,331,415; 6,339,142; 6,407,213; 6,417,335; 6,489,447; 6,586,206; 6,610,516; 6,620,918; 6,627,196; 6,716,602; 7,371,379; 7,390,660; 7,449,184; 7,485,704; 7,501,122; 7,807,799; 7,846,441; 7,892,549; 7,923,221; 7,993,834; 8,076,066; 8,357,301; 8,425,908; 8,440,402; 8,460,895; 8,512,983; 8,574,869; 8,633,302; 8,691,232; 8,771,988; 8,822,655; 9,047,438; 9,080,183; 9,249,218; 9,428,548; 9,428,766; 9,487,809; and 9,714,293.

B. Declare that one or more claims of U.S. Patent Nos. 6,331,415; 6,339,142; 6,407,213; 6,417,335; 6,610,516; 6,627,196; 6,716,602; 7,371,379; 7,449,184; 7,501,122; 7,807,799; 7,846,441; 7,892,549; 7,923,221; 7,993,834; 8,076,066; 8,357,301; 8,425,908; 8,440,402; 8,512,983; 8,574,869; 8,691,232; 8,822,655; 9,047,438; 9,080,183; and 9,249,218 are invalid.

C. Declare that U.S. Patent No. 6,407,213 is unenforceable.

D. Declare that this is an exceptional case in favor of Plaintiffs and award Plaintiffs their reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

E. Award Plaintiffs costs and expenses.

F. Award any and all such other relief as the Court determines to be just and proper, including pursuant to 28 U.S.C. § 2202.

Dated: February 8, 2018

GOODWIN PROCTER LLP
NEEL CHATTERJEE (173985)

/s/ *Neel Chatterjee*
Neel Chatterjee (173985)
Attorney for all Plaintiffs

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PROOF OF SERVICE
(FRCP 5)

I am a citizen of the United States and a resident of the State of California. I am employed In Menlo Park, CA and a member of the bar of this Court. I am over the age of eighteen years, and not a party to the within action. My business address is Goodwin Procter LLP, 135 Commonwealth Drive Menlo Park, CA 94025-1105. On the date set forth below I caused to be served the document described below in the manner described below:

- **REDACTED VERSION OF PLAINTIFFS' FIRST AMENDED COMPLAINT**

By electronic mail to the following counsel for Defendants, pursuant to their consent on February 7, 2018 to email service pursuant to Fed. R. Civ. P. 5(b)(E):

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Executed on February 8, 2018

/s/ Neel Chatterjee
Neel Chatterjee (173985)